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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,739	08/25/2003	Manuel Guzman Pastor	A34700 PCT USA-I	2301
21003	7590	11/21/2006	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112-4498			ANDERSON, JAMES D	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/647,739	GUZMAN PASTOR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 April 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. PCT/ES00/00450.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Applicants' arguments, filed 4/3/2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *Status of the Claims*

Claim 16 is currently pending and is the subject of this Office Action.

### *Priority*

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. § 119(a)-(d). The certified copy has been filed in parent Application No. PCT/ES00/00450, filed on November 22, 2000. A certified English translation was also filed in the parent application.

### *Claim Rejections - 35 USC § 112 – Second Paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant case, recitation of the phrase “including man” is indefinite because it is not clear whether this phrase is a claim limitation (*i.e.* is the intention to limit the treatment to only man).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. § 102(b) as being anticipated by The Merck Manual of Diagnosis and Therapy.

The instant claim is drawn to the treatment of one or more glioblastomas in a mammal comprising administering  $\Delta^9$ -tetrahydrocannabinol or  $\Delta^8$ -tetrahydrocannabinol.

The reference teaches that nausea and vomiting may be due to symptoms of disease processes or responses to stimuli such as drugs (antineoplastic chemotherapeutics), radiation, or motion (page 1281). Dronabinol ( $\Delta$ -9-tetrahydrocannabinol; THC) is approved to treat nausea and vomiting caused by cancer chemotherapy in patients who have failed to respond to conventional antiemetic therapy (page 1284). Doses are typically 5-15 mg/m<sup>2</sup> by oral administration (Table 103-7, page 1282).

The Merck Manual inherently teaches the claimed method because it teaches the administration of THC to patients to treat nausea and vomiting induced by chemotherapy or radiation treatment. As such, when THC is administered as an antiemetic to a patient undergoing

chemotherapy or radiation treatment for a glioblastoma, it will inherently treat the glioblastoma as instantly claimed. Further, headache and vomiting are often symptoms of intracranial neoplasms such as glioblastomas (page 1478-1479). Thus, when a patient presenting symptoms of nausea, headache, and/or vomiting is administered THC as an antiemetic, such administration will also inherently treat the underlying glioblastoma (if one exists).

It is the examiner's position that the prior art inherently teaches the claimed method because applicants have failed to sufficiently distinguish the patient population being treated in claim 16 from the larger population of patients who may present with nausea and vomiting due to chemotherapy and radiation treatment. Some of these patients are being treated for a glioblastoma. Thus, the prior art inherently teaches a method of treating a glioblastoma by administering THC.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

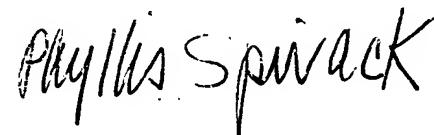
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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



James D. Anderson, Ph.D.  
Patent Examiner  
AU 1614

November 14, 2006



PHYLLIS SPIVACK  
PRIMARY EXAMINER